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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,103	02/08/1999	JEROME ASIUS	0198/00047	9613

7590 04/19/2002

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/242,103

Applicant(s)

ASIUS ET AL.

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 1, 2002 has been entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 27, on line 2, the Markush language is improper in that "consisting of the group" should be ---selected from the group consisting of--- in accordance with MPEP 2173.05(y).

With regard to claims 34 and 35, line 3, it is unclear what the concentration is based; e.g. the total weight of the gel or of the implant.

With regard to claim 36, line 2, the comma between "administration" and "according" makes it unclear what injectable implant is being freeze dried. The Examiner suggests deleting the comma in order to overcome this rejection.

Art Unit: 3738

### ***Claim Objections***

Claims 21, 28, and 29 are objected to because of the following informalities:

In claim 21, the language "microparticles in suspension in gel" is grammatically awkward. The Examiner suggests changing the language to read, "microparticles suspended in a gel" or "in a suspension within a gel" in order to be clear.

In claim 28 and 29, "Dalton" appears to be improper since there are more than one "Dalton." The Examiner suggests using "Daltons" in order to overcome this objection.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 21, 24, 27-31, and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Ron et al (US 5,597,897) wherein the sequestering agent and osteogenic

Art Unit: 3738

protein together of Ron et al are the gel as claimed and the polymeric particles of Ron et al are the microparticles or microspheres as claimed; see the entire document.

With regard to claims 30 and 31, the intrinsic viscosity is a function of both the polymer concentration and its molecular weight. Since the polymer concentration and solvent used is not specified, the claim limitation of intrinsic viscosity is quite broad. Furthermore, Ron et al discloses polymers of the same molecular weight range, but has not measured or determined the intrinsic viscosity thereof even though this property is inherently present therein. For this reason, the Examiner hereby asserts that the intrinsic viscosity of the Ron polymers is within the claimed range and hereby burdens the applicants to show otherwise via comparative testing thereof.

With regard to claim 36, Applicants are directed to Example 4 of Ron et al.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22, 23, 25, 26, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ron et al (US 5,597,897) alone.

With regard to claims 22 and 23, Ron et al discloses a particle concentration which is outside the claimed range. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to change the particle concentration because Applicants have not disclosed that

Art Unit: 3738

changing the particle concentration provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because the carrier would be removed in a relatively short time. Therefore, it would have been an obvious matter of design choice to modify Ron et al to obtain the invention as specified in the claims.

With regard to claim 25, Ron et al discloses a particle diameter that is outside the claimed range. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to change the particle diameter because Applicants have not disclosed that changing the particle diameter provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because the particle diameter is within the same order of magnitude as the prior art. Therefore, it would have been an obvious matter of design choice to modify Ron et al to obtain the invention as specified in the claim.

With regard to claim 26, Ron et al does not disclose the biodegradation time as claimed. However, Ron et al does specify that increasing the molecular weight does increase the biodegradation time; see column 3, lines 54-58. Therefore, it is the Examiner's position that it would have been obvious to change the molecular weight to adjust the biodegradation time in order to allow time for natural tissue replacement in different parts of the body. In addition, since biodegradation time is an inherent feature of the polymer, the Applicants are hereby burdened to show that the claimed biodegradation time of Ron et al is outside the claimed range.

Art Unit: 3738

With regard to claims 32 and 33, the residual monomer and solvent amount are not specified by Ron et al. However, since these measured properties are present in Ron et al to some extent, the Examiner hereby burdens Applicants to show that the amount present in the Ron et al material is outside the claimed range via comparative testing.

Claims 21-25 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scopelianos et al (EP 0711794) in view of Orly et al (WO 93/13755). Scopelianos meets the claim language except fails to disclose a gelation material for the liquid portion; see the entire document. However, Orly teaches that the use of a gelation material was known to the art; see the abstract. Hence, it is the Examiner's position that it would have been obvious to use the gelation material with other liquid components of Scopelianos to form a gel for the same reasons that Orly does the same and in order to improve the injection properties.

### ***Response to Arguments***

Applicant's arguments with respect to claims 21-36 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Art Unit: 3738

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
Art Unit 3738